European Association
Notified Bodies Medical Devices

TEAM-NB A I S B L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Tél.: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: info@quasys.com
Web: http://www.team-nb.org
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

**EUROPEAN COMMISSION**
Attention to Mr. Dalli
European Commissioner for Health and Consumer Policy
B - 1049 Brussels

February 6th, 2012.

Subject : Notified Body position regarding oversight and review of high risk devices

Dear Mr Dalli,

Following the various meetings and interactions with the Commission in the last month, you will find below Team-NB proposals regarding Notified Body oversight, including improvement possibilities learning from the PIP case, and the review of high risk devices. These represent our views based on our firm belief that the EU system of control of medical devices is well worked out and combines direct Competent Authority market surveillance with elements of pre-market dossier review and continuous market surveillance in annual audits by Notified Bodies. The system is a good basis for the GHTF model that is used in other parts of the world as the basis for new and improved legislation. It is clear that, like all regulatory regimes, there is scope for improvement but the basic regulatory structure is sound.

**Oversight**

To harmonise the quality of work of Notified Bodies and bring them to the desired high level of competence, Notified Body oversight should be at the EU level. To achieve this requires a pool of Competent Authority / Supervisory Institute auditors at the EU level that is as stable as possible over time. This will maintain and grow the competence and knowledge of auditing Notified Bodies . This team should lead the designation and monitoring audits of Notified Bodies. The central auditing body must have sufficient authority over audit team members from the respective Member States to ensure their conclusions are implemented in full in Notified Body operations.

**Review high risk devices (increased scrutiny for class III devices and novel technology)**

The Notified Body system should be strengthened to the desired level, through harmonisation, setting more specific requirements for the competence of reviewers, improving requirements of design dossiers, and details on their review by Notified Bodies. The alternative approach of building additional review steps will slow down the approval process, increase time to market and limit innovation of technology. These are key benefits that the EU system gives the patient, compared to other regimes, and is one of the reasons governments in other parts of the world are adopting similar regulatory models. We see the advantage of adding a “quality control” step at the EU level to validate the work of Notified Bodies, with the following characteristics:

- ✓ A small percentage of design dossiers will be selected based on established criteria that may change following developments in technology or Post Market Surveillance (PMS).
- ✓ Selection would be announced in the early application phase, so the process and expectations are transparent for all stakeholders.

European Association
Notified Bodies Medical Devices

TEAM-NB A I S B L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Tél.: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: info@quasys.com
Web: http://www.team-nb.org
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

- ✓ The additional review would follow draft review by the Notified Body and be done by a central EU body in a limited timeframe of e.g. 30 days, who would have the benefit of benchmarking reviews of similar devices.
- ✓ An even better possibility could be a system in which the European Body reviews a design dossier after certification without announcing it beforehand. Such a system would be more helpful to enhance the entire system, as it would stimulate a uniform high level of reviews rather than facilitate a focused high level effort in a few selected cases. The focused high level effort would distort the market and unfairly disadvantage the individual companies that happened to be picked.

**Improvement possibilities learning from the PIP case**

The PIP case, realising this is a very serious deliberate attempt to commit fraud leading to high and unacceptable safety risks for patient, in our view could best serve as a stimulant to further improve the system from within. A legislative system of market control cannot be constructed to guarantee against all cases of such deliberate malpractice. However, improvements may result from the lessons learned:

- ✓ Safety officer or responsible person
  Mandating each legal manufacturer to dedicate a Qualified Person with high level of qualification, responsible with legal status & personal liability who will have responsibility of batch releases, technical file content, risk analyses, compilation of feedback from post market surveillance and protected from the Management to take decisions not in favour of the company, could help forward a culture shift toward a higher compliance level. Some member states have already adopted such an approach and this experience should form the basis of any new requirement.
- ✓ Access to Post Market Surveillance data
  Notified Bodies support the use of registries for a wider range of implants and making PMS data and other relevant information available to Notified Bodies so they can fully implement that into the review process. Notified Bodies will be able to challenge the manufacturers on the basis of trend analysis. Sharing information between Competent Authorities and Notified Bodies will strengthen the independence of the supervision, in which Notified Bodies no longer have to rely on the manufacturers' own data in their supervision
- ✓ Clarify content of technical file content in the legislation.
  As identified above, these specifications could be more specific in the new legislation in order to be absolutely clear what level of technical documentation is required. Today only the STED summary format is defined. It is important to clarify the requirements as some Manufactures consider MEDDEV as guidance documents only and not mandatory. The mandates towards product standards might be including more quantitative requirements being generated to serve as a State of the Art reference.
- ✓ Product inspection by Notified Bodies
  Setting specific requirements for the method of auditing of medical device manufacturers such as sampling actual products and following the audit trail to cover all aspects of design and manufacturing from raw material to distribution and back.
- ✓ Hotline (whistle blowing)
  Realising this will lead to numerous investigations, attempts have been successful elsewhere.
- ✓ Unannounced visits.
  Today almost all audits are announced beforehand, as this is a requirement in ISO 17021 and IAF accreditation. Adding elements of unannounced product inspections as defined above on top of current regular quality management system based audits

European Association
Notified Bodies Medical Devices

TEAM-NB A I S B L.
Boulevard Frère Orban 35A
B – 4000 Liège BELGIQUE
Tél.: + 32 (0)4 254 55 88
Fax: + 32 (0)4 254 55 89

E-mail: info@quasys.com
Web: http://www.team-nb.org
Bank ING: 340-1517487-57
IBAN BE09 3401 5174 8757

would have the benefit of surprise and therewith raise the bar to engage in fraudulent practice. A system based on justification given by authorities on a case by case basis or on high profile product categories would fit best as an improvement over current practice, and would be aligned with the use of such visits in other jurisdictions.

We hope that the proposals put forward by Team-NB will help in the improvement and harmonization of the new legislative framework in the sector. We would like to suggest a face to face meeting for further discussion on these and other topics related to the revision of legislation to further assist you in the effort where possible.

Yours faithfully

[redacted]

Dr. Gert BOS
President